ANESTHESIOLOGY

# Clinical Evaluation of a High-fidelity Upper Arm Cuff to Measure Arterial Blood Pressure during Noncardiac Surgery

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## EDITOR'S PERSPECTIVE

### What We Already Know about This Topic

- Oscillometric blood pressure assessments are routine in surgical patients and most clinical environments but are considerably less accurate than generally appreciated

### What This Article Tells Us That Is New

- A novel noninvasive upper arm system using hydraulic coupling technology provides accurate and precise estimates of the systolic, mean, and diastolic pressure compared with direct measurements of the femoral arteries

## ABSTRACT

**Background:** In most patients having noncardiac surgery, blood pressure is measured with the oscillometric upper arm cuff method. Although the method is noninvasive and practical, it is known to overestimate intraarterial pressure in hypotension and to underestimate it in hypertension. A high-fidelity upper arm cuff incorporating a hydraulic sensor pad was recently developed. The aim of the present study was to investigate whether noninvasive blood pressure measurements with the new high-fidelity cuff correspond to invasive measurements with a femoral artery catheter, especially at low blood pressure.

**Methods:** Simultaneous measurements of blood pressure recorded from a femoral arterial catheter and from the high-fidelity upper arm cuff were compared in 110 patients having major abdominal surgery or neurosurgery.

**Results:** 550 pairs of blood pressure measurements (5 pairs per patient) were considered for analysis. For mean arterial pressure measurements, the average bias was 0 mmHg, and the precision was 3 mmHg. The Pearson correlation coefficient was 0.96 ($P < 0.0001$; 95% CI, 0.96 to 0.97), and the percentage error was 9%. Error grid analysis showed that the proportions of mean arterial pressure measurements done with the high-fidelity cuff method were 98.4% in zone A (no risk), 1.6% in zone B (low risk) and 0% in zones C, D, and E (moderate, significant, and dangerous risk, respectively). The high-fidelity cuff method detected mean arterial pressure values less than 65 mmHg with a sensitivity of 84% (95% CI, 74 to 92%) and a specificity of 97% (95% CI, 95% to 98%). To detect changes in mean arterial pressure of more than 5 mmHg, the concordance rate between the two methods was 99.7%. Comparable accuracy and precision were observed for systolic and diastolic blood pressure measurements.

**Conclusions:** The new high-fidelity upper arm cuff method met the current international standards in terms of accuracy and precision. It was also very accurate to track changes in blood pressure and reliably detect severe hypotension during noncardiac surgery.

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ARTERIAL hypotension is a common adverse event during surgery, particularly after anesthesia induction and during surgical bleeding.[1,2] In large retrospective cohort studies, both the number and duration of hypotensive events have been shown to be associated with the incidence of postoperative stroke, myocardial injury, acute kidney injury, and death.[3–9] Two recent randomized controlled trials suggest that close control of intraoperative arterial blood pressure may reduce the risk of postoperative organ dysfunctions.[10,11] It is important to note that both studies used invasive blood pressure measurement through a radial artery catheter.

In most patients having noncardiac surgery, arterial blood pressure is automatically measured at regular time intervals (typically every 3 to 5 min) with the oscillometric upper arm cuff method.[12,13] Although this method is noninvasive and practical, clinical studies suggest that hypotensive events are not precisely identified. In a retrospective analysis of 27,022 pairs of invasive and noninvasive blood pressure measurements, Lehman *et al.*[14] describe clinically significant

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discrepancies. During hypotension, noninvasive systolic blood pressure values were systematically higher than invasive systolic blood pressure values. In a large comparison study on 15,310 noncardiac surgical cases, Wax *et al.*[15] report that the oscillometric cuff method overestimates low blood pressure and underestimates high blood pressure compared with radial artery catheter measurements. Differences and SDs became progressively larger below the invasive systolic, diastolic, and mean blood pressures of 111, 80, and 95 mmHg, respectively.[15] It has recently been shown that an oscillometric blood pressure measurement cannot reliably detect hypotension in emergency patients.[16] Remarkably, the three studies used oscillometric devices from different manufacturers, which could indicate a systematic methodologic problem of oscillometric blood pressure measurement for the correct detection of hypotension.

The oscillometric upper arm cuff method has been revisited by a German startup (UP-MED) that was recently merged with Philips (Philips Medizin Systeme Boeblingen, Germany). Conventional oscillometric blood pressure cuffs are basically constructed the same way using air-filled cuffs and tubes made of rubber or flexible plastics. This is not optimal for the signal-to-noise ratio of the detectable pulse signals (oscillations) because both air and rubber are highly compliant. Thus, a normal pulse pressure of around 40 mmHg results typically in measured oscillations with amplitudes between 1 and 4 mmHg depending on the arterial pressure, pulse pressure, arterial stiffness, subcutaneous fatty tissue, the upper arm composition, and the compliance of the cuff.[17,18] In contrast, the newly developed high-fidelity cuff is much less compliant because it has a semirigid conical shell and incorporates a hydraulic sensor pad with a pressure transducer (fig. 1). Therefore, by hydraulic coupling to the upper arm, the signal-to-noise ratio largely increases, leading to "high-fidelity" tissue pressure pulse contour with all characteristics of an arterial pulse contour (fig. 2).

We hypothesized that such a technical approach could offer good accuracy and precision when measuring blood pressure. Therefore, we designed the present study to compare blood pressure measurements done with the new high-fidelity cuff method and reference femoral artery catheter measurements in patients having noncardiac surgery.

## Materials and Methods

This is a prospective, multicenter, comparative study of a new noninvasive high-fidelity blood pressure measurement method done in the departments of anesthesiology at the Ludwig-Maximilians-Universität München Hospital, the University Hospital of Bonn, and the RoMed Hospital in Rosenheim, Germany. The study was approved by the ethical committee of Ludwig-Maximilians-Universität Munich (#276-13, approved on August 26, 2013, and amendments approved on April 4, 2014). Written informed consent was obtained from all patients the day before scheduled surgery.

We studied anesthetized and mechanically ventilated patients from the age of 18 yr having either major abdominal surgery or major neurosurgery in the supine position and in whom blood pressure was continuously monitored with four or five French femoral arterial catheters as part of the clinical routine. For noninvasive blood pressure measurements with the new high-fidelity tissue pressure pulse wave method, three different cuff sizes were available and selected according to the middle upper arm circumference (fig. 1). The cuff design with its conical form is based on biometric upper arm data acquired in previous studies in more than 250 volunteers and patients (German governmental grant No. KF2664502AK0 from Zentrales Innovationsprogramm Mittelstand).

Before the cuff was attached to the upper arm, the tissue pressure transducer of the cuff was zeroed at the height of the sensor pad at the inner side of the cuff. During application of the cuff to the upper arm, care was taken to keep the resting attachment pressure between 5 and 15 mmHg. The femoral artery catheter was connected to a pressure transducer and zeroed at midchest level. In addition, the heights of the transducer of the femoral artery and the transducer of the cuff were precisely tuned and controlled by separate fluid-filled tubes according to principle of communicating tubes. Before the measurements started, the clinical investigator carried out quality assurance and documented the results (details in Supplemental Digital Content 1, http://links.lww.com/ALN/C442).

The operating principle of the newly developed high fidelity cuff is based on hydraulic coupling of a fluid filled pressure sensor pad in a temporarily semirigid shell-encased upper arm cuff to record tissue pressure pulse waves that result from brachial artery pulsation (fig. 1). The new cuff compresses the upper arm by its integrated pneumatic actuator encasing the semirigid conical shell and thus raises tissue pressure, like a conventional upper arm cuff. The tissue pressure is transferred to the hydraulic pressure sensor pad across muscles, subcutaneous fat, connective tissue, and skin, resulting in a high-fidelity tissue pressure waveform with a visible dicrotic notch (fig. 2). The determination of systolic blood pressure (SBP), mean arterial pressure (MAP), and diastolic blood pressure (DBP) with the new hydraulic coupling method is based on evaluating changes in tissue pressure waveform parameters during the period of actuator pressure increase. Tissue pressure waveform parameters include both amplitude and area parameters, and their combination yields a tissue pulsation power parameter for each tissue pressure pulse. Tissue pulsation power parameter values of multiple adjacent tissue pressure pulses during actuator pressure increase are combined to generate a tissue pressure waveform function, which, after smoothing, forms a tissue pressure waveform curve.

A first SBP is read at the tissue pressure waveform curve's upper envelope at the point of time when tissue pressure waveform curve reaches a predetermined percentage (ax)

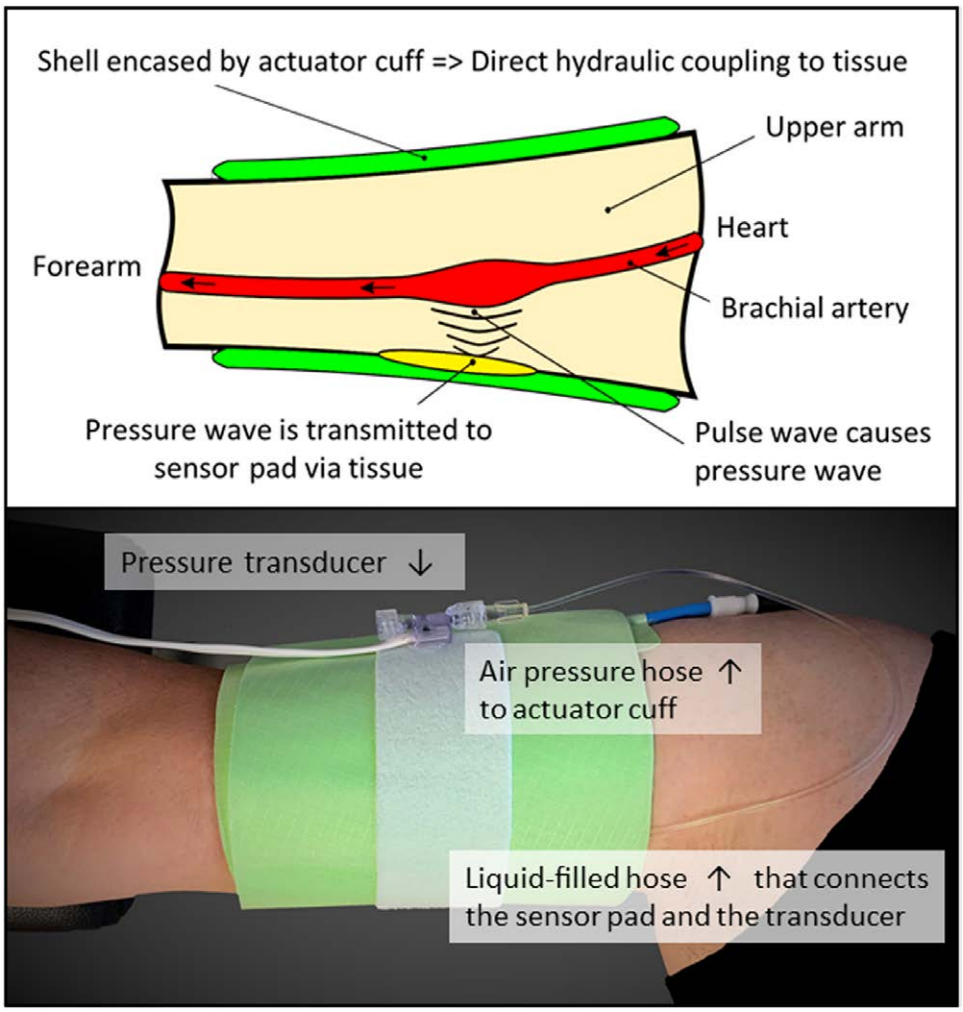


**Fig. 1.** Schematic representation (longitudinal section) and photo of a high-fidelity cuff on the right upper arm. The sensor pad for recording the tissue pressure pulsations is located on the inside of the cuff near the brachial artery. The sensor pad is connected to the pressure transducer *via* a pressure hose filled with liquid. The pressure transducer is attached to the outside of the high-fidelity cuff at heart level. Air pressure is supplied *via* the blue hose to the actuator cuff that surrounds the semirigid shell. Find more details in https://patents.google.com/patent/WO2018210931A1/en.

of its maximum. A second SBP is calculated in the same way from another tissue pressure waveform curve based on a different tissue pulsation power parameter implementation. The final SBP is a weighted average of the first and second value. A first MAP is read as the tissue clamping pressure at the point of time when tissue pressure waveform curve reaches a predetermined percentage (bx) of its maximum. A second MAP is calculated in the same way from another tissue pressure waveform curve based on a different tissue pulsation power parameter implementation. The final MAP is a weighted average of the first and second value. DBP is calculated from final SBP and final MAP as: $DBP = 0.9 \times MAP - 0.4 \times (SBP - MAP) + 2.4$. Further details are disclosed in the patent application WO2018210931A1. Access with the link: https://patents.google.com/patent/WO2018210931A1/en (accessed July 13, 2020).

To ensure optimal synchronization between noninvasive and invasive measurements, femoral intraarterial pressure measurements were averaged beat-by-beat over the period used for noninvasive cuff measurements. To improve future clinical adoption, a fast mode measurement was also tested off-line.

Investigators could perform as many cuff measurements as they wanted during the surgical procedure focusing on clinical events associated with different ranges in blood pressure. Through careful observation and intermittent flushing with signs of damping, the investigators tried to provide

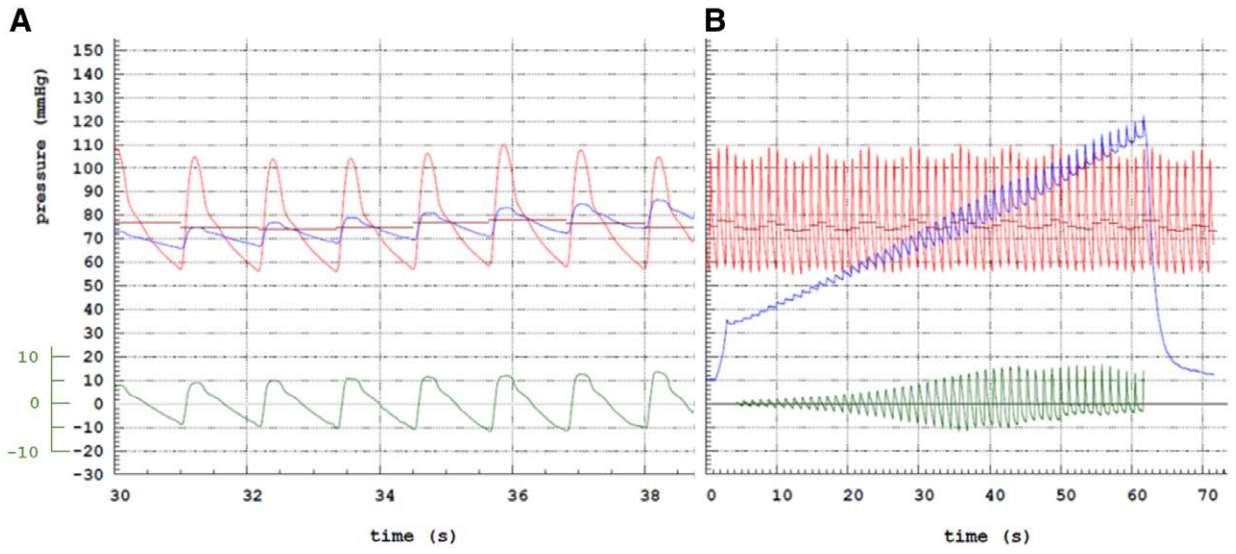


**Fig. 2.** Original offline graphics for evaluation of a paired arterial blood pressure measurement in a 37-yr-old male patient having neurosurgery. The *red curves* indicate the invasive arterial blood pressure, the *brown lines* show the MAP of each arterial pulse, and the *blue curves* show the tissue pressure pulsations as recorded by the sensor pad of the high-fidelity cuff. The *green curves* are the linearized signals of the tissue pressure pulsations and are enhanced by a factor of 2 for better visibility. (*A*) Section of the measurement with increasing tissue pressure pulse amplitudes and visible dichrotic notch on the tissue pulse contour. (*B*) Summary of the entire measurement over a period of 62 s.

flawless femoral artery pressure recordings. Standard mode oscillometric blood pressure values of the high-fidelity cuff were displayed during measurements for controlling proper function, but they were not used for making any therapeutic decisions, which were exclusively based on femoral intraarterial measurements of blood pressure.

## Statistical Analysis

Because we conducted the study in the operating room under clinical conditions, we expected that a significant number of measurements would not meet the predefined quality criteria (Supplemental Digital Content 1, http://links.lww.com/ALN/C442). We therefore planned to recruit at least 150 patients with at least 5 paired measurements. A data analysis and statistical plan was written and included correlation analysis and Bland–Altman with multiple measurements per subject analysis.[19] After accessing the data, the statistical plan was supplemented with a four-quadrant plot to track changes in blood pressure and an error grid analysis.[20,21]

To be included in the analysis, each pair of measurements had to pass a quality test that was carried out by two experts. They checked the absence of any artifacts in both the tissue pressure waveforms and the femoral artery pressure recordings and overdamping of the latter especially. In addition, they excluded measurements with unstable femoral artery pressures occurring during the cuff measurements, *i.e.* changes of MAP more than 10 mmHg in 60 s, the period in which the high-fidelity cuff captures tissue pressure pulsations within the pulse pressure range (see details and figures in the Supplemental Digital Content 1, http://links.lww.com/ALN/C442). We have analyzed the same number of paired measurements (n = 5) per patient so that each patient is weighted equally in the analysis. We selected the lowest, the highest, and three equally distributed invasive intraarterial measurements in between and the corresponding cuff measurements for analysis (for details see Supplemental Digital Content 1, http://links.lww.com/ALN/C442).

The statistical analysis was carried out at the Department of Anesthesiology, University Hospital of the Ludwig-Maximilians-Universität Munich using MedCalc Statistical Software Version 19.1 (MedCalc Software BV, Belgium; https://www.medcalc.org; 2019) and checked by two authors according to the principle of double control. We compared MAP, SBP, and DBP measured using the high-fidelity upper arm cuff (cuff method) and the femoral arterial catheter (reference method) by calculating the Pearson correlation coefficient $r$ with $P$ value and 95% CI and the mean ± SD of the differences between the two methods according to Bland–Altman for clustered observations.[19,22] The percentage error was calculated as described by Critchley and Critchley.[23] To assess the clinical relevance of our findings, first we compared them with the Association for the Advancement of Medical Instrumentation criteria, which set acceptable limits to 5 mmHg for the bias and 8 mmHg for the SD. Then we performed an error grid analysis as recently proposed by Saugel *et al.*[21,24] The error grid analysis enables a

risk level to be assigned to each pair of MAP values. We calculated the proportions of measurements in risk zones A–E, with A indicating no risk, B indicating low risk, C indicating moderate risk, D indicating significant risk, and E indicating dangerous risk for the patient because of no or wrong clinical interventions because of measurement errors. Finally, we quantified the sensitivity and specificity of the high-fidelity upper arm cuff to detect hypotension defined by a MAP of less than 65 mmHg. This MAP threshold was selected because a large observational study and a recent consensus article have reported significant relationships between postoperative complications, death, and arterial blood pressure as soon as the MAP is less than 65 mmHg.[7,25]

In addition, the ability of the high-fidelity upper arm cuff to track changes in blood pressure values (direction of change analysis) from the previous measurement was investigated. To do so, we computed four-quadrant plots and performed a concordance analysis for MAP, as previously described.[20,26] The four-quadrant plot shows changes between consecutive blood pressure measurements obtained using the high-fidelity brachial cuff (*y* axis) and the femoral arterial catheter (*x* axis) in a scatter plot. We defined a 5-mmHg exclusion zone at the center of the plot to exclude very small arterial pressure changes that may not be clinically relevant. Based on the data points outside the exclusion zone, we calculated the concordance rate as the proportion (percentage) of concordant data pairs to all data pairs.[20,26]

## Results

Between November 13, 2013, and April 5, 2018, we sequentially enrolled and analyzed 153 patients having elective major abdominal surgery or neurosurgery at three participating study sites. According to predefined quality criteria, the data of 43 patients were discarded because of severe protocol violation, technical, or patient-related reasons. Typical reasons for protocol violation were incorrect zeroing of invasive arterial line, use of radial artery line for blood pressure measurements, or inappropriate size of the high-fidelity cuff. Technical reasons were defective recordings and consistent overdamping of invasive arterial measurements, whereas atrial fibrillation was a patient-related reason for exclusion (fig.S1, Supplemental Digital Content 1, http://links.lww.com/ALN/C442).

The 110 patients (61 male and 49 female) selected had elective major abdominal surgery (n = 55) or neurosurgery (n = 55). The main characteristics of the patients under study are presented in table 1. Patients received general anesthesia with either propofol and remifentanil (neurosurgery) or balanced anesthesia with opioids and volatile anesthetics (abdominal surgery).

A total of 1,887 paired measurements passed the quality check and were available for the analysis. The descriptive analysis showed a high weight both for individual patients with many measurements and for MAP values between 75 and 85 mmHg, which is why we decided to select an equal number of measurements per patient that covered the measured pressure range. In this way, we were able to achieve a more homogeneous distribution of the paired measurements (Supplemental Digital Content 1, http://links.lww.com/ALN/C442).

We selected 550 paired measurements of arterial blood pressure for comparisons (5 measurements per patient with minimum, maximum and 3 intermediate values to cover the measured arterial pressure range; Supplemental Digital Content 1, http://links.lww.com/ALN/C442). The blood pressure measurements with the new high-fidelity cuff required a mean actuator pressure time of 64 s (SD ± 10 s) up to 20 mmHg of tissue pressure above the systolic blood pressure (standard mode). In the fast mode, the tissue pressure increased to a maximum of 85% (SD ± 4.7%) of the systolic pressure with a shortening of mean actuator time to 37 s (SD ± 5.3 s).

Overall, we observed a very close correlation (Pearson's r = 0.96; $P < 0.0001$; 95% CI, 0.96 to 0.97) and a very good agreement (mean of the differences = 0 ± 3 mmHg) between MAP values (fig. 4). The percentage error was 9% in the standard mode (table 2). The mean of the differences was not correlated in any way with high or low MAP values (figs. 3 and 4). The fast mode showed a correlation coefficient of 0.95 ($P < 0.0001$; 95% CI, 0.95 to 0.96), a mean of the differences of −2 (SD 4) mmHg, and a percentage error of 10%. Similar results were found for systolic and diastolic blood pressures. The Association for the Advancement of Medical Instrumentation criteria were also met, when using both the standard and the fast mode (table 2).

Among the 550 paired measurements, we identified 83 hypotensive events (reference MAP less than 65 mmHg) in 44 patients based on invasive femoral artery measurements. The new high-fidelity cuff method was able to detect invasive MAP of less than 65 mmHg with a sensitivity of 84% (95% CI, 74 to 92%) and a specificity of 97% (95% CI, 95% to 98%). The new cuff method using hydraulic coupling met the Association for the Advancement of Medical Instrumentation criteria for critically low MAP values as well (mean of the differences = 1 ± 3 mmHg for invasive MAP values less than 65 mmHg).

Error grid analysis showed that the proportions of MAP measurements were 98.4% in risk zone A (no risk), 1.6% in zone B (low risk), and 0% in zones C, D, and E (moderate,

**Table 1.** Main Characteristics of the Study Population

| Patient Characteristics | Total or Mean Value | Range |
|---|---|---|
| Patients | 110 | |
| Men/women | 61/49 | |
| Age, yr | 61 | 20–86 |
| Body weight, kg | 75 | 42–136 |
| Height, cm | 171 | 150–198 |
| Body mass index, kg/m$^2$ | 26 | 18–35 |
| Body surface area, m$^2$ | 1.8 | 1.3–2.6 |
| Mid-upper arm circumference, cm | 29 | 23–38 |

**Table 2.** Comparison between Femoral Artery and High-fidelity Cuff Measurements

| | Pearson Correlation Coefficient (95% CI)* | Mean of the Differences (SD), mmHg | 95% Limits of Agreement, mmHg | Percentage Error, % |
|---|---|---|---|---|
| Standard mode | | | | |
| Mean arterial pressure | 0.96 (0.96–0.97) | 0 (3) | –7 to 6 | 9 |
| Systolic arterial pressure | 0.96 (0.95–0.97) | 0 (5) | –10 to 10 | 9 |
| Diastolic arterial pressure | 0.93 (0.92–0.94) | 0 (4) | –8 to 7 | 12 |
| Fast mode | | | | |
| Mean arterial pressure | 0.95 (0.95–0.96) | –2 (4) | –9 to 6 | 10 |
| Systolic arterial pressure | 0.92 (0.91–0.93) | –1 (7) | –16 to 13 | 13 |
| Diastolic arterial pressure | 0.93 (0.92–0.94) | –2 (4) | –9 to 6 | 12 |

*Sample size: n = 550; all *P* values for Pearson correlation coefficient were less than 0.0001.

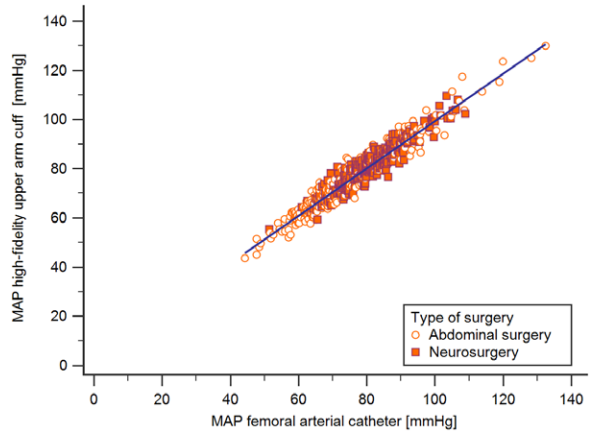


**Fig. 3.** Scatter diagram of mean arterial pressure (MAP) measurements done with the femoral arterial catheter and the high-fidelity upper arm cuff. In total, 550 measurements were taken in 110 patients having abdominal surgery or neurosurgery (five measurements per patient; Pearson correlation coefficient r = 0.96; $P < 0.0001$; 95% CI, 0.96 to 0.97).

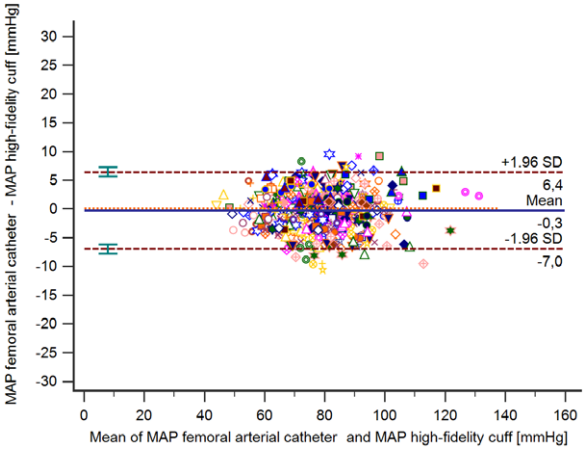


**Fig. 4.** Bland–Altman plot with multiple measurements per patient of mean arterial pressure (MAP) done with the femoral arterial catheter and the high-fidelity upper arm cuff. The plot shows a mean difference of –0.3 mmHg, an upper limit of agreement of 6.4 (CI, 5.6 to 7.3) mmHg, and a lower limit of agreement of 7.0 (CI, –7.9 to 6.2) mmHg. There is a marker for each of the 110 patients in the graphic.

significant, and dangerous risk; fig. 5). Error grid analysis for systolic pressures revealed 99.8% in zone A and 0.2% in zone B. Changes in noninvasive MAP were closely correlated with changes in invasive measurements (r = 0.99). When using an exclusion zone of 5 mmHg, the concordance rate between the two methods was 99.7% (fig. 6). Analyses of paired measurements (n = 1,887) of MAP that had met the predefined quality criteria are shown in the Supplemental Digital Content 2 (http://links.lww.com/ALN/C443) for both standard mode and fast mode.

## Discussion

Our study shows that the new high-fidelity cuff method meets the Association for the Advancement of Medical Instrumentation accuracy and precision criteria for MAP, SBP, and DBP measurements. It also shows that the new cuff method is very accurate to track changes in MAP and reliably enables the detection of hypotension during general anesthesia and surgery with high sensitivity and specificity.

In the present study, we used femoral artery catheter measurements as the reference standard. In a classical article, Kroeker and Wood[27] showed a high agreement in systolic, mean, and diastolic pressure between both A. brachialis and A. femoralis by using intraarterial catheterization in 12 healthy male physicians. Simultaneous intraarterial recording of brachial and femoral pressures did not show differences in adult cardiac surgery patients before start of cardiopulmonary bypass.[28,29] In addition, comparison of intraarterial brachial and femoral pressures in children did not show

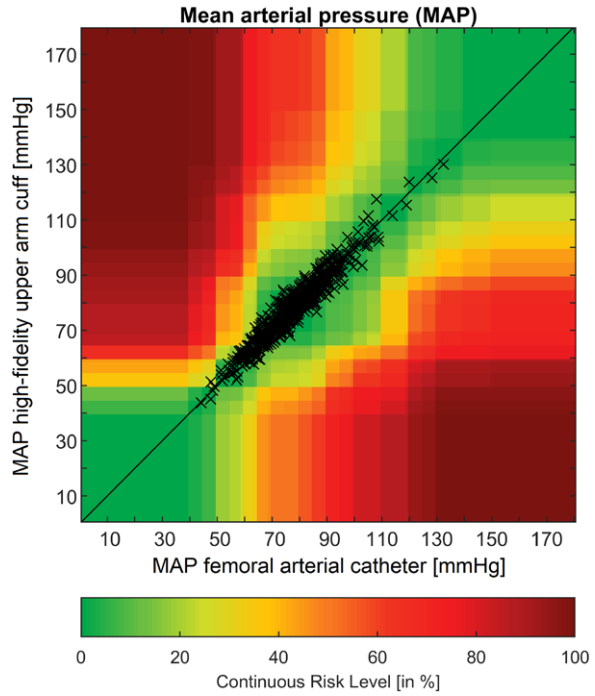


**Fig. 5.** Comparison of mean arterial pressure (MAP) measurements done with the femoral arterial catheter and the high-fidelity upper arm cuff using the error grid analysis proposed by Saugel *et al.*[21,24] Pairs of measurements in the *green areas* do not lead to risk for the patient. Zone A includes 541 (98.4%) measurements, and zone B includes 9 (1.6%) measurements.

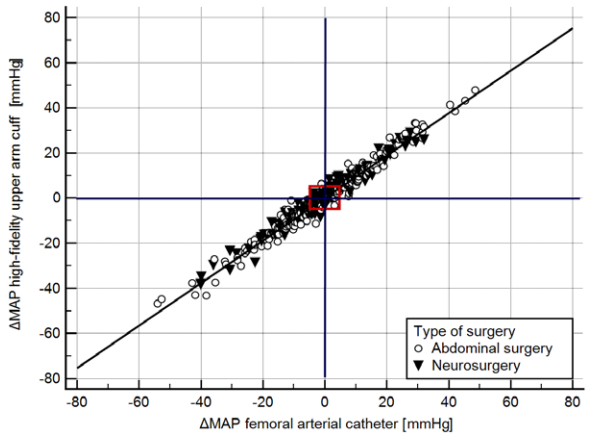


**Fig. 6.** Comparison between changes in mean arterial pressure (MAP) measured with the femoral arterial catheter and the high-fidelity upper arm cuff (ΔMAPcuff). Changes in MAP less than 5 mmHg are excluded from the comparison. *Red square*, exclusion zone. In total, 299 measurements were taken in 103 patients (Pearson correlation coefficient, r = 0.99; $P < 0.0001$; 95% CI, 0.98 to 0.99). The concordance rate between the two methods was 99.7%.

differences either.[29] In contrast, the radial intraarterial blood pressure is significantly different from the brachial intraarterial blood pressure because the radial artery, as opposed to brachial and femoral artery, does not represent a major artery. Radial artery measurements would therefore not be suitable as a reference method.[28,30] Our results demonstrate that measurements done with the new cuff by noninvasive hydraulic coupling of the brachial artery pulsation were in close agreement with the femoral artery measurements.

Arterial lines enable continuous blood pressure monitoring but are associated with complications such as vascular injuries, thromboembolism, pseudoaneurysm, hemorrhage, and infection.[31,32] Therefore, their use is restricted to patients at risk for adverse hemodynamic events. In this context, radial catheters are frequently used, but radial measurements may differ from aortic pressures because of the physiologic pulse amplification phenomenon. Indeed, brachial artery pressures are more reliable and accurate than radial artery pressures when compared with central aortic pressures.[33] There are specific clinical situations, such as continuous infusion of vasopressors, sepsis, or liver transplantation, in which radial systolic and mean pressures may significantly underestimate central arterial pressures and may lead to increased use of vasopressors.[34–38] For these reasons, a technical approach to capture close to central arterial pressures is highly desirable in critical clinical conditions.

In many patients having noncardiac surgery, blood pressure is monitored with an oscillometric upper arm cuff. Although accurate in normotensive phases of anesthesia, this method has significant limitations during hypotension that can lead to clinically relevant overestimation of blood pressure in adults, young children, and infants.[15,39] Using the new high-fidelity upper arm cuff method, we did not find a bias during hypotension, and we were able to detect hypotension (MAP less than 65 mmHg) with high sensitivity and specificity. The level of precision of MAP measured with the new high-fidelity upper arm cuff was high and was also preserved during hypotension. This suggests that the new high-fidelity cuff method may be more accurate and precise than classical oscillometric methods.

Several techniques have recently been proposed for the noninvasive and continuous estimation of arterial blood pressure.[40] In general, these techniques utilize peripheral arterial measurement sites. Validation studies have yielded conflicting results for both radial applanation tonometry and finger volume clamp methods.[41–44] A meta-analysis of clinical studies investigating the accuracy and precision of tonometric and volume clamp methods concluded that they do not meet the AAMI criteria.[45] In addition, volume clamp methods measure a finger blood pressure, which is prone to signal loss caused by peripheral vasoconstriction (*e.g.* cold extremities, vasopressor therapy). However, a reliable blood pressure measurement is required, especially in critical situations.[14]

Several limitations of this study must be considered for the correct interpretation of our results. First, an investigator who was not involved in patient care performed the measurements in this study, ensuring that the study protocol was followed exactly. Second, we only included measurements fulfilling predefined quality criteria and selected five measurements per patient, which covered a broad blood pressure range. The strength of this study is that we have clearly shown that the new method has no systematic bias across a wide range of blood pressure, especially in the hypotensive pressure range in patients having noncardiac surgery.[14,15]

Because we did not measure blood pressure with a regular upper arm cuff at the same time, we cannot say that the new method is superior to the oscillometric method. Studies are needed to compare the respective performance of the new high-fidelity cuff methods and the classical noninvasive methods in the same patient population at risk for hemodynamic events and hypotension.

In future, the new high-fidelity cuff method will also enable the reconstruction of a blood pressure pulse curve from sampling and weighting single tissue pressure pulses taken from close to diastole to systole for a period of more than 30 s. Using an appropriate pulse contour algorithm would facilitate assessment of cardiac output and, in mechanically ventilated patients, pulse pressure variation and other dynamic parameters to predict fluid responsiveness.[46,47] Therefore, future studies will also have to investigate whether this new high-fidelity cuff method could assess estimations of cardiac output and fluid responsiveness parameters under clinical conditions. This may open the door to a more rational intraoperative management of blood pressure and flow on a noninvasive basis without changing clinical routine.[48]

## Conclusions

In patients having major noncardiac surgery, we found tight correlation and good agreement between arterial blood pressure measurements done simultaneously with a new high-fidelity upper arm cuff using the noninvasive hydraulic coupling technique and the reference femoral artery measurements. The new cuff method was also very accurate to track changes in mean arterial pressure and to detect severe hypotension during anesthesia and surgery.

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## Competing Interests

Dr. Briegel is a co-inventor of the international patent application "Method for non-invasively determining at least one blood pressure value, measurement apparatus and system for determining blood pressure non-invasively" (WO2018210931A1). As an employee of Klinikum der Ludwig-Maximilians-Universität, Dr. Briegel has transferred his rights to the invention to the employer, wherein the pertaining therefrom intellectual property rights were subsequently transferred to former UP-MED GmbH, for which Dr. Briegel received a remuneration payment as defined by German law. Dr. Briegel acknowledges lecture fees unrelated to this work from CSL Behring, Marburg, Germany. Drs. Hoeft and Kreitmeier received fees for advice on cuff designs, technical implementation, and clinical application from the former UP-MED GmbH. Dr. Hoeft reports an ongoing financial relationship with Philips. Dr. Pfeiffer is co-inventor of the following international patent applications: "Method for non-invasively determining at least one blood pressure value, measurement apparatus and system for determining blood pressure non-invasively" (WO2018210931); "Blood Pressure Measuring System Comprising a Kinking-Proof Shell" (WO2014121805A1, also published as US2015359446A1); and a not-yet-published patent application related to an improved and quicker method of determining blood pressure during cuff's inflation. Dr. Pfeiffer reports former UP-MED GmbH having received payments in 2011 and 2012 through German governmental grant "Zentrales Innovationsprogramm Mittelstand (ZIM)" KF2664502AK0. Further Dr. Pfeiffer, as former owner of UP-MED GmbH, which was merged with Philips Medizin Systeme Böblingen GmbH in 2018, had and continues to have financial interest in the technology. Philips Medizin Systeme Böblingen GmbH is also Dr. Pfeiffer's current employer. In addition, Dr. Pfeiffer is also the founder of Pulsion Company, which is today a part of GETINGE group AB. The other authors declare no competing interests.

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